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Date: June 14, 2010

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(Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/798,739
Confirmation No.: 6427
Filing Date: March 10, 2004
Inventor(s): George D. HERMANN et al.
Title: METHOD AND DEVICE FOR USE IN MINIMALLY INVASIVE
APPROXIMATION OF MUSCLE AND OTHER TISSUE
Examiner: Melissa K. Ryckman
Group Art Unit: 3773

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Washington, D.C. 22313-1450

Sir:

This is an appeal brief to the final Office Action mailed May 12, 2009. Applicant submitted a Notice of Appeal on November 12, 2009 for which an appeal brief is due on January 12, 2010. Filed herewith is a Petition and fee for a 5-month extension of time, thereby extending the deadline for response to June 12, 2010. Accordingly, this brief is timely filed.

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I. Real Party in Interest

This application is assigned to Fogarty, Thomas J., M.D. of Portola Valley, California.

II. Related Appeals and Interferences

There are no related Appeals and Interferences.

III. Status of Claims

Claims 7, 8, 11, 28-33 and 41-49 were rejected. Claims 1-6, 9-10, 12-27, 34-40 were canceled. Claims 7, 8, 11, 28-33 and 41-49 are currently under appeal.

IV. Status of Amendment

No amendment was made subsequent to final rejection.

V. Summary of Claimed Subject Matter

The independent claims on appeal are Claims 7 and 41. All noted specification locations below are for exemplary purposes only and non-limiting.

Claim 7 is to a tissue approximating device, generally shown in Figure 19. The claim recites first and second jaw members (shown generally as 11 and 12, and also 194 and 195) having terminal ends moving toward one another (see e.g., figures 7, 8, 19 and para [0065]), the moveability of the terminal ends defining a plane of coaptation (also see e.g., figures 7, 8, 19 and paras [0042] and [0065]);

The claim also recites a tissue engaging rod (generally shown as 8 and 196). The claim recites that the tissue engaging rod has a tissue engaging portion that extends generally out of the plane of coaptation in a first position (see figs. 1B and 19 and paras [0042] and [0065]). The claim also recites that the tissue engaging rod (8 and 196) is moveable to a second tissue engaging position that transects the plane of coaptation thereby positioning tissue contacted by the tissue engaging rod between the first jaw member and the tissue engaging rod, and between the second jaw member and the tissue engaging rod (see fig. 19 and para [0065]).

The claim also recites that the tissue engaging rod is configured to extend independently of the first jaw member (see figs. 1B and 19 and para [0065]).

Claim 41 is to a tissue approximating device, generally shown in Figure 19. The claim recites first and second jaw members (shown generally as 11 and 12, and also 194 and 195) having proximal ends moveable toward one another (see e.g., figures 7, 8, 19 and para [0065]), the moveability of the proximal ends defining a plane of coaptation (also see e.g., figures 7, 8, 19 and paras [0042] and [0065]).

The claim also recites a tissue engaging rod (generally shown as 8 and 196). The claim recites that the tissue engaging rod has a tissue engaging portion that can extend generally out of the plane of coaptation in a first position (see figs. 1B and 19 and paras [0042] and [0065]). The claim recites that the tissue engaging rod is moveable to a second tissue engaging position that transects the plane of coaptation thereby positioning tissue contacted by the tissue engaging rod between the first jaw member and the tissue engaging

rod, and between the second jaw member and the tissue engaging rod (see figs. 1B and 19 and paras [0042] and [0065]).

The claim also recites that the tissue engaging rod is configured to extend independently of the first jaw member (see figs. 1B and 19 and para [0065]).

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 7, 8, 11, 28-33 and 41-49 are unpatentable under 35 U.S.C. 102(b) over Williams (U.S. Patent No. 3,996,937).

VII. Argument

A. Double Patenting

Claims 7, 8 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-18 of U.S. Patent No. 6,706,048.

Applicant has filed a terminal disclaimer herewith, overcoming the rejection.

Applicant requests withdrawal of this rejection.

B. 35 U.S.C. §102, Claim 7, 11, 28-31, 41, and 43-47

The Office Action rejected claims 7, 11, 28-31, 41, and 43-47 under 35 U.S.C. §102(b) as being anticipated by Williams (U.S. Patent No. 3,996,937). Applicant submits that the Office Action fails to establish that the claims 7, 11, 28-31, 41, and 43-47 are anticipated by Williams.

MPEP §2131 states "To anticipate a claim, the reference must teach every element of the claim." Applicant respectfully submits that Williams fails to teach every element of the rejected independent claims 7 and 41, and therefore inherently fails to teach every element of dependent claims 11, 28-31, and 43-47.

Applicant's independent claims 7 and 41 recite "A tissue approximating device comprising...a tissue engaging rod, said tissue engaging rod having a tissue engaging portion that can extend generally out of the plane of coaptation in a first position, said tissue engaging rod moveable to a second tissue engaging position that transects the plane of coaptation thereby positioning tissue contacted by the tissue engaging rod between the first jaw member and the tissue engaging rod, and between the second jaw member and the tissue engaging rod; and

wherein the tissue engaging rod is configured to extend independently of the first jaw member."

Independent claim 7 additionally is limited to comprising "first and second jaw members having terminal ends moveable toward one another, the moveability of the terminal ends defining a plane of coaptation"; whereas independent claim 41 is limited to comprising "first and second jaw members having proximal ends moveable toward one another, the moveability of the proximal ends defining a plane of coaptation."

Applicant disagrees with the rejection for the following reasons:

First, the Office Action states that Williams teaches “first and second jaw (14,16) members having terminal ends moveable toward one another, the moveability of the terminal ends defining a plane of coaptation (Fig. 5)”. (P. 2)

However, Williams’ first jaw member 14 does not have a terminal end, as required by the claims. The first jaw member 14 is integral with and becomes second jaw member 16. Williams even states: “a single length of wire or rod is formed extending between terminal ends 28 and 35 so that the device is unitary.” col. 4, lines 19-21. As shown in Figures 2 and 4, neither of the terminal ends 28 and 35 is on the first jaw member 14.

Furthermore, Williams’ jaw members 14 and 16 do not move toward one another, as required by the claims. As shown clearly in bottom views in Figures 2 and 4, and stated in the quote shown supra from col. 4, lines 19-21, Williams’ jaw members 14 and 16 are part of a single, integrated structure, not taught to move toward each other. In col. 3, lines 20-21, Williams also states, “the device is formed of a single length of spring wire or rod”, and col. 3, lines 24-25 read: “These outside members [14 and 16] are joined by a U-shaped bridge 26.” The U-shaped bridge clearly prevents the distal ends (which are not even terminal ends) of the jaw members 14 and 16 from moving toward each other.

Also, the side views of Figures 1 and 3 of Williams show that the U-shaped bridge 26 between the distal ends of the first and second jaw members 14 and 16 lies in a different plane than the remainder of the jaw members 14 and 16 and is out of plane with the plane of coaptation. The lack of co-planarity between the U-shaped bridge 26 and the rest of the jaw members 16 and 14 is shown at the far right in Figures 1 and 3.

Col. 3, lines 26-29 of Williams states: “the bridge is preferably offset angularly from the plane extending along the length of clamp members 14 and 16 as shown in Figure 1.” More discussion of the angular offset of 26 occurs through to col. 3, lines 30-59.

Figure 4 shows that the coaptation occurs in the device proximal to the U-shaped bridge 26, and therefore out of plane with the U-shaped bridge, as seen by the location of the vessel 30 with respect to the U-shaped bridge 26 in Figure 4. So the distal ends of the jaw

members, which are neither terminal nor movable toward each other, do not define the plane of coaptation, as required by the claim.

Accordingly, Williams fails to teach numerous elements of the limitation of first and second jaw (14,16) members having terminal ends moveable toward one another, the moveability of the terminal ends defining a plane of coaptation, as required by the claim.

Second, the office action states that Williams satisfies the claim limitation: "wherein the tissue engaging rod is configured to extend independently of the first and second jaw member (Fig. 3)."

However, Williams' alleged tissue engaging rod 18 does not extend, nor does it move independently of the members 14 or 16 because these members are all part of a unitary device, as described explicitly by Williams: "a single length of wire or rod is formed extending between terminal ends 28 and 35 so that the device is unitary." Col. 4, lines 19-21. Williams also states: "the device is formed of a single length of spring wire or rod." Col. 3, lines 20-21. Extension of the alleged tissue engaging rod 18 independent of the first and second jaw members 14 and 16 is generally impossible since the elements are integrated with each other. When the handle is squeezed, the squeezing will have an impact on the motion of all the members. The Williams device would need some other element, not taught by Williams, to isolate the motion of the first and second jaw members 14 and 16 when attempting to extend the member 18.

Third, the office action states that Williams satisfies the claim limitation: "moving the tissue engaging rod (18) comprises retracting the distal end of the tissue engaging rod from a position more distal to the distal end of the first jaw member to a position less distal of the distal end of the first jaw (Fig. 4)."

However, Williams' member 18 does not move distal or proximal to either of the jaw members 14 and 16. Member 18 merely rotates towards and away members 14 and 16, with the members 14 and 16 doing the same to member 18. There is no proximal or distal movement of the members relative to each other (see the right sides of Figs. 1 and 3).

In view of the above, Williams fails to satisfy all the limitations of the independent claims, and therefore all of the limitations of the dependent claims. Applicant requests withdrawal of this rejection.

C. 35 U.S.C. §103, Claim 8, 32, 33, 42, 48 and 49

The Office Action rejected claims 8, 32, 33, 42, 48 and 49 under 35 U.S.C. §103(a) as being unpatentable over Williams (U.S. Patent No. 3,019,790). Applicant submits that the Office Action fails to establish a proper prima facie case of obviousness over claims 8, 32, 33, 42, 48 and 49.

Williams fail to teach the limitations of the respective independent claims, as stated supra. Additionally, the Office Action states a conclusory justification and fails to provide a reason why such a modification would be desirable. MPEP § 2144.04 (V)(C) states that the separability of a component must be desirable to be obvious, but the Office Action states that the making the portions separable would merely make the device perform "equally as well", not that it would be better or desirable. In fact, it would counter common sense to want to have a surgical device that has separable working components in case of separation during a procedure.

Likewise, the Office Action states merely that replacing a "hollow material would perform equally as well as a solid material." This statement is conclusory and also fails to explain a reason why a solid material would be desirable.

Furthermore, the Office Action fails to address the subject matter of claims 33 and 49.

In view of the above, Applicant requests withdrawal of this rejection.

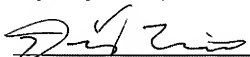
D. Summary

Applicant believes all outstanding issues raised in the previous Office Action are addressed herein and that the claims are in condition for allowance.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No.

FGRTNA00602. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David A. Levine', is written over a horizontal line.

David A. Levine
Registration No. 48,821

Customer No. 40518
Levine Bagade Han LLP
2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 242-4214
Fax: (650) 284-2180

VIII. Claims Appendix

1. – 6. (Canceled).

7. (Previously presented): A tissue approximating device comprising:

first and second jaw members having terminal ends moveable toward one another, the moveability of the terminal ends defining a plane of coaptation; and

a tissue engaging rod, said tissue engaging rod having a tissue engaging portion that can extend generally out of the plane of coaptation in a first position, said tissue engaging rod moveable to a second tissue engaging position that transects the plane of coaptation thereby positioning tissue contacted by the tissue engaging rod between the first jaw member and the tissue engaging rod, and between the second jaw member and the tissue engaging rod; and

wherein the tissue engaging rod is configured to extend independently of the first jaw member.

8. (Previously presented): The device of Claim 7 wherein said first jaw member includes a lumen extending longitudinally through at least a portion of the first jaw member.

9. - 10. (Canceled).

11. (Previously presented): The device of Claim 7 wherein said tissue engaging rod is pivotally attached to said first and second jaw members.

12. - 27. (Canceled).

28. (Previously presented): The device of Claim 7, wherein the tissue engaging rod is configured to extend independently of the second jaw member.

29. (Previously presented): The device of Claim 7, further comprising a first handle integral with the first jaw member, and further comprising a second handle integral with the second jaw member.

30. (Previously presented): The device of Claim 7, further comprising a hinge, wherein the first jaw and the second jaw members are rotatably attached to the hinge.

31. (Previously presented): The device of Claim 7, wherein the first and second jaw members have inner surfaces facing toward one another.

32. (Previously presented): The device of Claim 7, wherein the first jaw member comprises a distal portion and a proximal portion, and wherein the distal portion is detachable from the proximal portion.

33. (Previously presented): The device of Claim 32, wherein the distal portion forms a substantially non-zero angle with respect to the proximal portion.

34 – 40. (Canceled)

41. (Previously presented): A tissue approximating device comprising:
first and second jaw members having proximal ends moveable toward one another, the moveability of the proximal ends defining a plane of coaptation; and
a tissue engaging rod, said tissue engaging rod having a tissue engaging portion that can extend generally out of the plane of coaptation in a first position, said tissue engaging rod moveable to a second tissue engaging position that transects the plane of coaptation thereby positioning tissue contacted by the tissue engaging rod between the first jaw member and the tissue engaging rod, and between the second jaw member and the tissue engaging rod; and
wherein the tissue engaging rod is configured to extend independently of the first jaw member.

42. (Previously presented): The device of Claim 41 wherein said first jaw member includes a lumen extending longitudinally through at least a portion of the first jaw member.

43. (Previously presented): The device of Claim 41, wherein said tissue engaging rod is pivotally attached to said first and second jaw members.

44. (Previously presented): The device of Claim 41, wherein the tissue engaging rod is configured to extend independently of the second jaw member.

45. (Previously presented): The device of Claim 41, further comprising a first handle integral with the first jaw member, and further comprising a second handle integral with the second jaw member.

46. (Previously presented): The device of Claim 41, further comprising a hinge, wherein the first jaw and the second jaw members are rotatably attached to the hinge.

47. (Previously presented): The device of Claim 41, wherein the first and second jaw members have inner surfaces facing toward one another.

48. (Previously presented): The device of Claim 41, wherein the first jaw member comprises a distal portion and a proximal portion, and wherein the distal portion is detachable from the proximal portion.

49. (Previously presented): The device of Claim 48, wherein the distal portion forms a substantially non-zero angle with respect to the proximal portion.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.